510(k) Summary

Contact Details

Applicant Name: Acumed LLC
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Kara Budor, Regulatory Specialist
503-207-1412

Date Prepared: June 19, 2013

SEP 30 2013

Device Name

Trade Name: Acumed Anatomic Radial Head System
Acumed Anatomic Radial Head Long Stems
Acumed ARH Slide-Loc™ System

Common Name: Elbow Hemi-, Prosthesis

Classification: 21 CFR 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis

Class: II

Product Code: KWI

Legally Marketed Predicate Device(s)

The Anatomic Radial Head System cleared in 2004 (K041858) serves as the predicate device.

Device Description

The Acumed Anatomic Radial Head Long Stems and the Acumed ARH Slide-Loc™ System include modular heads and stems with accessories to anatomically replace the proximal portion of the radius and restore the natural articulation of the radial head with the radial notch of the ulna and capitulum of the distal humerus.

Intended Use/Indications for use

The Acumed Anatomic Radial Head System, the Anatomic Radial Head Long Stems, the ARH Slide-Loc™ System, and accessories are designed specifically for:

1. Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radiohumeral and/or proximal radio-ulnar joint with: joint destruction and/or subluxation, resistance to conservative treatment.
2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty.

The device is intended to be press fit or cemented.

Substantial Equivalence Comparison

The basic comparison between the Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System to the Acumed Anatomic Radial Head System is given in the table below.

	Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System	**Predicate**
Material	Titanium alloy per ASTM F136 Cobalt Chromium per ASTM 1537	Titanium alloy per ASTM F136 Cobalt Chromium per ASTM 1537
Head Diameter	18mm to 30mm	20mm to 28mm
Stem Diameter	5mm to 12mm	6mm to 10mm
Stem Length	25mm to 65mm	22mm
Stem Finish	Grit Blast	Grit Blast
Head-to-Stem Connection	Slide-Loc™ groove and rail connection with neck component and/or Morse Taper	Morse Taper
Head Configuration	Neutral or Left/Right Specific	Neutral
Stem Configuration	Neutral or Left/Right Specific	Neutral
Provided Sterile / Non-sterile	Sterile	Sterile

The Anatomic Radial Head Long Stems, the ARH Slide-Loc™ System, and the Anatomic Radial Head System all include implants and instruments used to replace the radial head. There are some differences, but none of them raise new issues of safety or effectiveness. The Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System are substantially equivalent to the Acumed Anatomic Radial Head System.

Non-clinical Testing

The Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System underwent static and cyclic load testing to characterize their strength.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Acumed, LLC
Ms. Kara Budor
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

September 30, 2013

Re: K131845
Trade/Device Name: Acumed Anatomic Radial Head System
Acumed Anatomic Radial Head Long Stems
Acumed ARH Slide-Loc™ System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: August 30, 2013
Received: September 3, 2013

Dear Ms. Budor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth L. Frank -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131845

Device Name: Acumed Anatomic Radial Head System
Acumed Anatomic Radial Head Long Stems
Acumed ARH Slide-Loc™ System

Indications for Use:

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1. Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radiohumeral and/or proximal radio-ulnar joint with: joint destruction and/or subluxation, resistance to conservative treatment.
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3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty.

The device is intended to be press fit or cemented.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley Ph.D.
Division of Orthopedic Devices